authorities, as noted above, are responsible for supervising FCs as part of their ongoing prudential regulation and supervision of such FCs, will enforce the RTS, which are directly applicable in the Member States, and will take all measures necessary to ensure that those rules are implemented. Thus, the Commission finds that the EC, through the competent authorities, has the necessary powers to supervise, investigate, and discipline entities for compliance with its margin requirements and recognizes the relevant competent authorities' ongoing efforts to detect and deter violations of, and ensure compliance with, the margin requirements applicable in the EU.

V. Conclusion

As detailed above, the Commission has noted several differences between the Final Margin Rule and the EU margin rules. However, having considered the scope and objectives of the margin requirements for uncleared swaps under the laws of the EU,[202] whether such margin requirements achieve comparable outcomes to the Commission's corresponding margin requirements,[203] and the ability of the Member State competent authorities to supervise and enforce compliance with the margin requirements for non-centrally cleared OTC derivatives under the laws of the EU,[204] the Commission has determined that the EU margin rules are comparable in outcome to the Final Margin Rule.

As noted above, the Final Margin Rule's regulatory objective is to ensure the safety and soundness of CSEs in order to offset the greater risk to CSEs and the financial system arising from the use of swaps that are not cleared. The EU margin rules require counterparties to apply robust risk-mitigation techniques to their bilateral relationships to reduce counterparty credit risk and to mitigate the potential systemic risk that could arise. Moreover, the EU margin rules achieve comparable outcomes to the Final Margin Rule in the following specific areas: The products and entities subject to the EU's margin requirements; the treatment of inter-affiliate derivative transactions; the methodologies for calculating the amounts of initial and variation margin; the process and standards for approving models for calculating initial and variation margin models; the timing and manner in which initial and variation margin must be collected and/or paid; any threshold levels or amounts; risk management controls for the calculation of initial and variation margin; eligible collateral for initial and variation margin; the requirements of custodial arrangements, including segregation of margin and rehypothecation; margin documentation requirements; and the cross-border application of the EU's margin regime. Finally, based on the long history of regulatory cooperation between the Commission and Member State competent authorities with supervisory and enforcement authority under the RTS, the Commission finds that the EC, through the competent authorities, has the necessary powers to supervise, investigate, and discipline entities for compliance with its margin requirements, and recognizes the relevant authorities' ongoing efforts to detect and deter violations of, and ensure compliance with, the margin requirements applicable in the EU.

Accordingly, a CSE that is subject to both the Final Margin Rule and the EU's margin rules with respect to an uncleared swap that is also a non-centrally cleared OTC derivative may rely on substituted compliance for all aspects of the Final Margin Rule and the Cross-Border Margin Rule. Any such CSE that, in accordance with this comparability determination, complies with the EU margin rules, would be deemed to be in compliance with the Final Margin Rule but would remain subject to the Commission's examination and enforcement authority.[205]

Issued in Washington, DC, on October 13, 2017, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Appendix to Comparability Determination for the European Union: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Quintenz and Behnam voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2017–22616 Filed 10–17–17; 8:45 am]

BILLING CODE 6351–01–P

International/MemorandaofUnderstanding/index.htm.

[202] *See* § 23.160(c)(3)(i).

[203] *See* § 23.160(c)(3)(ii). As discussed above, the Commission's Final Margin Rule is based on the BCBS/IOSCO Framework; therefore, the Commission expects that the relevant foreign margin requirements would conform to such Framework at minimum in order to be deemed comparable in outcome to the Commission's corresponding margin requirements.

[204] *See* § 23.160(c)(3)(iii). *See also* § 23.160(c)(3)(iv) (indicating the Commission would also consider any other relevant facts and circumstances).

[205] *See* § 23.160(c)(4).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2017–N–5160]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Organophosphate Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the organophosphate test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the organophosphate test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 18, 2017. The classification was applicable on August 8, 2013.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD, 20993–0002, 301–796–5866.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the organophosphate test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to

these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and 21 CFR part 807.

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval (PMA) application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence'').

Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on May 2, 2013, finding the Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS (liquid chromatography-tandem mass spectrometry (the two ''MS'' next to each other denote ''tandem'')) not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On May 31, 2013, Elizabeth Hamelin, on behalf of the Centers for Disease Control and Prevention, Division of Laboratory Sciences/National Center for Environmental Health, submitted a request for classification of the Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 8, 2013, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.3652. We have named the generic type of device organophosphate test system, and it is identified as a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the confirmation and investigation of organophosphate exposure.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ORGANOPHOSPHATE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
False Positive	(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. (2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.
False Negative	(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. (2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.
Public Health Risk from Incorrect Test Results.	(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response. (2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 862.3652 to subpart D to read as follows:

§ 862.3652 Organophosphate test system.

(a) *Identification.* An organophosphate test system is a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the confirmation and investigation of organophosphate exposure.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response.

(2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

Dated: October 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–22590 Filed 10–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS MICHAEL MONSOOR (DDG 1001) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective October 18, 2017 and is applicable beginning October 3, 2017.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Kyle Fralick, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS MICHAEL MONSOOR (DDG 1001) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the forward masthead light at a height not less than 6 meters above the hull; Annex I, paragraph 2(g) pertaining to the placement of sidelights above the hull of the vessel; Rule 30(a)(i) and Annex I, paragraph 2(k) pertaining to the vertical separation between anchor lights, and the location of the forward anchor light at a height of not less than 6 meters above the hull; Annex I, paragraph 3(a), pertaining to the horizontal separation between the forward and after masthead lights; Annex I, paragraph 2(i)(iii), pertaining to the vertical spacing of task lights; and Annex I, paragraph 3(c), pertaining to the task lights placed at a horizontal distance of not less than 2 meters from the fore and aft centerline of the vessel. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended by:

■ a. In Table One, adding in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001);